

Remarks

Claims 1-13, 32, 36-57, 60-66, 68, and 69 are pending in the subject application. Applicant gratefully acknowledges the Examiner's indication that claims 1-13, 32, 36-57, 60, 61, 64, 65, and 68 are allowed. By this Amendment, Applicant has canceled claims 62, 63, 66, and 69. Accordingly, claims 1-13, 32, 36-57, 60, 61, 64, 65, and 68 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicant notes that the Examiner has not indicated, in any Office Action thus far in prosecution, whether the drawings filed in the subject application are acceptable. Accordingly, Applicant respectfully requests that the Examiner review the figures filed in the subject application and confirm in the next Official Communication that the drawings are acceptable.

Claims 62, 63, 66, and 69 are rejected under 35 USC §112, first paragraph, as lacking sufficient written description. The Examiner asserts that the subject specification does not disclose an adequate number of mutations, other than the  $\Delta F508$ ,  $\Delta I507$ , S549R, and G551D described in the subject specification, to support the claims. Applicant respectfully asserts that there is adequate written description for the claimed invention. The mutation encompassed by the claims can be any possible mutation in the CFTR amino acid sequence. An ordinarily skilled artisan can readily mutate any amino acid in the CFTR sequence. Moreover, in addition to the several mutations specifically described in the subject specification, numerous other mutations in CFTR polypeptides were known in the art at the time of the present invention. See, for example, the CFTR protein database at the internet address <http://us.expasy.org/cgi-bin/niceprot.pl?P13569>, and numerous scientific reviews such as that by Tsui L.C., "Mutations and Sequence Variations Detected in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Gene: A Report from the Cystic Fibrosis Genetic Analysis Consortium," *Hum. Mutat.*, 1992, Vol. 1(3): 197-203. Satisfaction of the written description requirement can be met by looking to the teachings in the specification and to teachings in the prior art. It is well established in patent law that a specification need not disclose that which is well known in the art. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986) citing *Lindemann Maschinenfabrik v. American Hoist and Derrick*, 221 USPQ 481 (Fed. Cir. 1984), ("... a patent need not teach, and preferably omits, what is well known in the art."). Further, satisfaction of the written description requirement does not require description of all possible

embodiments or species encompassed by the claims. However, in order to expedite prosecution of the subject application to allowance, Applicant has canceled claims 62, 63, 66, and 69 by this Amendment. It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicant's agreement with or acquiescence in the Examiner's position. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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